

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Sweeney, Patrick J.
Title: SPINAL DISC PROSTHESIS SYSTEM
Appl. No.: 10/619,757
Filing Date: 07/15/2003
Examiner: Philogene, Pedro
Art Unit: 3733

DECLARATION UNDER 37 C.F.R. §1.131

Commissioner for Patents
PO Box 1450
Alexandria, Virginia 22313-1450

I, Patrick J. Sweeney, state and declare that:

1. I am the inventor of all of the claims of the above-referenced patent application.
2. Prior to June 2, 2003, I conceived in the United States the invention described and claimed in each of the currently pending claims of the above-referenced application.
3. Prior to June 2, 2003, I provided an invention disclosure to my law firm containing drawings and descriptive text of various embodiments of the invention claimed in the above-referenced patent application.
4. A copy of the invention disclosure is attached hereto as Exhibit A. Portions of Exhibit A have been redacted.
5. The drawings and descriptive text of Exhibit A provide evidence of the conception of the invention claimed in the above-referenced application.

6. Prior to June 2, 2003, attorneys from my law firm scanned the invention disclosure and transmitted the scanned document between attorneys Matthew Martin, Mark Kassel, Michael Houston, and Michelle Manning as indicated in the e-mail correspondence attached hereto as Exhibit B. Portions of Exhibit B have been redacted, including the transmittal dates. The transmittal dates are all prior to June 2, 2003.

7. On June 24, 2003, Michelle Manning sent a draft of the above-referenced patent application to me as indicated in the e-mail attached hereto as Exhibit C.

8. On July 15, 2003, the above-referenced patent application was filed with the United States Patent and Trademark Office.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing therefrom.

Date

9/8/06

By

Patrick J. Sweeney

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SUMMARY OF INVENTION

An artificial disc prosthetic replacement system is described. Placed via anterior, anterolateral or lateral approach, it may be revised multiple times from multiple approaches. This will be useful as the disc replacement elements wear out or are technologically outmoded. This system will allow interchangeability of multiple disc technologies for revision purposes. It will also allow conversion to an interbody fusion without removal of the entire system.

A scaffolding system is the basis of fixation that will, in general, rest on the periphery of the vertebral endplate. While a scaffold covering the entire endplate, or portions of it, is also conceived, preserving the central endplate will allow revision fusion. This scaffold will initially be cobalt chrome, but titanium, plastic, ceramics, and other composites will be tested. This scaffold will anchor to the superior and inferior endplates via pegs, spikes or screws and may have a coating to assist with bony ingrowth. Future attachment to a vertebral prosthesis is possible.

Cutouts or anchoring points will be positioned around the scaffold allowing firm fixation of various replaceable disc components. Other anchoring points will be positioned to allow for removable buttresses that may serve as extension or lateral bending or flexion constraints. These may also serve as retention devices for disc replacements that are not rigidly attached to the vertebrae or the scaffold. These buttresses may have variable sizing to vary the degree of constraint in one or more directions.

Disc replacement technologies that are compatible comprise mechanical, hydraulic, gas or fluid filled, elastomeric, and functionally similar discs. These may be rigidly fixed to the scaffold or rest on high friction plates or be placed in a mobile fashion on low friction plates affixed to the scaffolds, such as polished metal or ceramic.

An initial disc replacement model will involve high friction metallic plates rigidly fixed to the superior and inferior scaffolds in a removable manner. Extension and lateral flexion blocks will be attached to the scaffold. These blocks will initially be metallic, also serving to contain the removable disc element. One three-component prosthesis is described that will rest between the high friction plates. A larger cylindrical cup will contain a reciprocally positioned smaller cup. The relative size of these cups may vary to control the degree of global constraint. The cups will initially be metallic with high friction outer surfaces while other materials including ceramic will follow. The high friction surfaces will allow the prosthesis to rest securely within the constraints of the outer structure. Alternatively, a prosthesis with a low friction outer surface could be positioned on low friction outer plates in a manner that would permit movement between the plates and prosthesis while still being easily revised. The larger outer cup would have a convex internal surface that will articulate with a load bearing, force absorbing construct resting in the smaller cup. This load bearing construct will have a concave surface to complement the opposing internal surface. This relationship may be reversed. The load bearing construct may be metallic and be positioned inside the smaller cup in a

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stressed manner allowing it to function in a spring like fashion. The shape of this support will initially be cruciate but other shapes are envisioned. This support may also be elastomeric, or hydrogel resting snugly inside the smaller cup. The outer cups would also serve to contain wear debris that might otherwise stimulate an inflammatory response as often seen in deteriorating, peripheral joint replacements. A "nested" cup design may be used, providing flexibility in the axis-of-motion location. In this situation an internal cup would be integral to both of the opposing outer cups. This cup would contain the articulating elements and be positioned away from the center of the larger cups, thus allowing for compensation of any difficulties with scaffold placement and proper location of the axis-of motion.

This system may also be useful in performing primary interbody fusions that may later be converted to arthroplasty if a primary arthroplasty is not possible. The fusion could be removed anteriorly or laterally and replaced with a disc prosthesis while keeping the scaffold in place. A special insert formed to bear the stresses of the interspace, containing osteoconductive as well as osteoinductive material would rest in the scaffold allowing bone growth across a defined area. This would be easily disrupted at the time of arthroplasty allowing removal of the insert and replacement with the prosthesis.

Other objects and advantages of the invention will become apparent upon reading the following detailed description and upon reference to the drawings. Throughout the drawings, like reference numerals refer to like parts.

BRIEF DESCRIPTION OF THE DRAWINGS

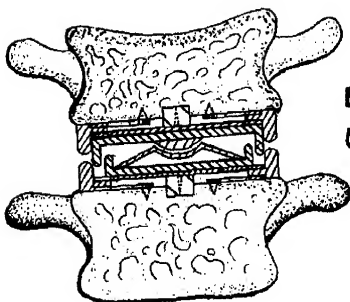
FIG. 1 is a

DETAILED DESCRIPTION

While the invention will be described in connection with a preferred embodiment and procedure, it will be understood that it is not intended to limit the invention to this embodiment or procedure. On the contrary, it is intended to cover all alternatives, modifications, and equivalents as may be included within the spirit and scope of the invention as defined by the appended claims.

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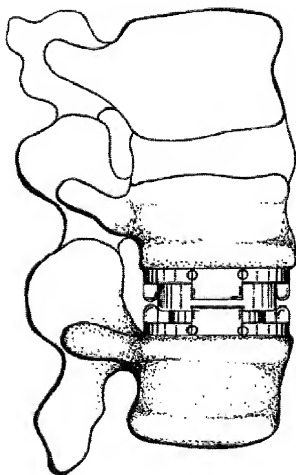


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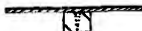
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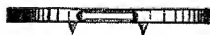
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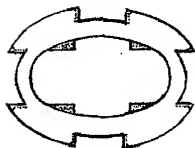
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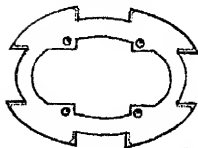
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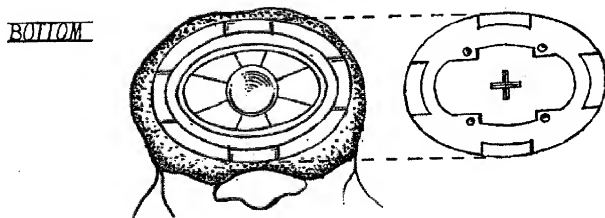
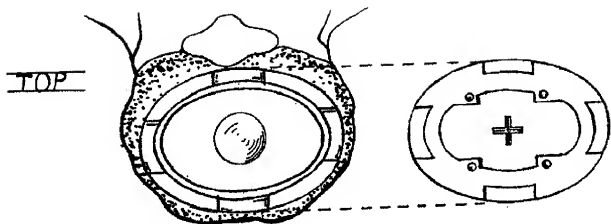
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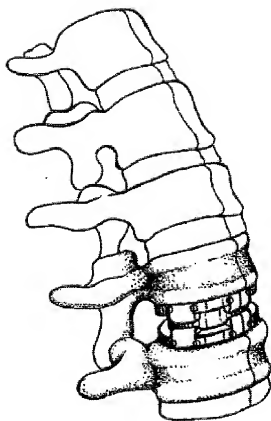
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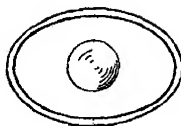
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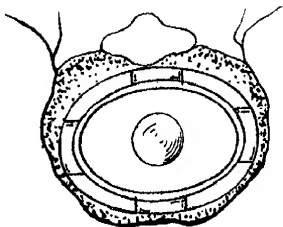
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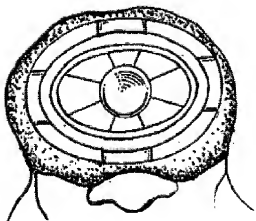


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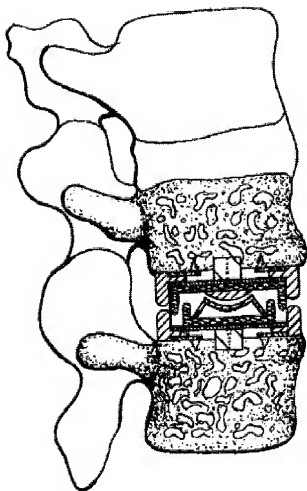
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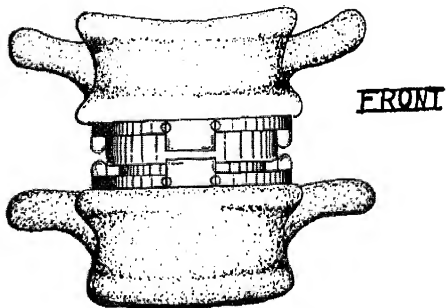
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Manning, Michelle



From: Houston, Michael R.
Sent:
To: Manning, Michelle
Subject: FW: invention disclosure from Dr. Patrick Sweeney

Attachments: Document 1.pdf; Document 2.pdf; Document 3.pdf



Document 1.pdf (2 MB)



Document 2.pdf (627 KB)



Document 3.pdf (58 KB)

are the disclosures from Dr. Sweeney. The third one is the one I printed out on fenestrated screws. The first two regard discs.

Mike

-----Original Message-----

From: Kassel, Mark A.
Sent:
To: Houston, Michael R.
Subject: FW: Invention disclosure from Dr. Patrick Sweeney

Mark A. Kassel
Foley & Lardner
150 E. Gilman Street
Madison, Wisconsin 53701
Ph. 608.258.4272
Fax 608.258.4258

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-----Original Message-----

From: Martin, Matthew R.
Sent:
To: Kassel, Mark A.
Cc: Green, Edward
Subject: Invention disclosure from Dr. Patrick Sweeney

Mark,

Here are the scanned documents from this morning's meeting. I will mail you photocopies as well.

Matt

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An artificial disc prosthetic replacement system is described. Placed via anterior, anterolateral or lateral approach, it may be revised multiple times from multiple approaches. This will be useful as the disc replacement elements wear out or are technologically outmoded. This system will allow interchangeability of multiple disc technologies for revision purposes. It will also allow conversion to an interbody fusion without removal of the entire system.

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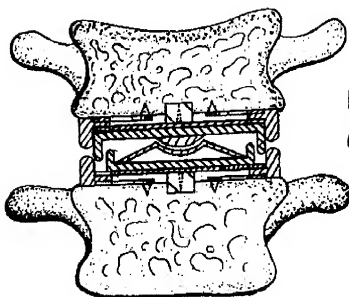
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DETAILED DESCRIPTION

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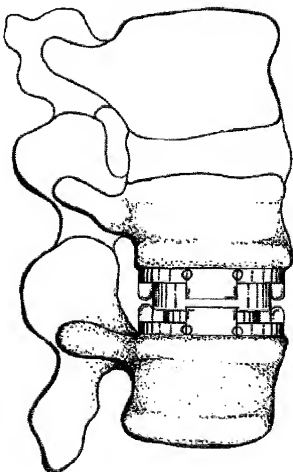


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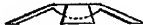


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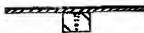
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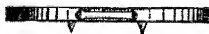
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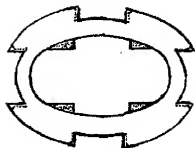
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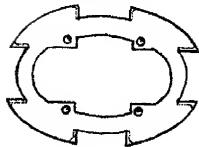
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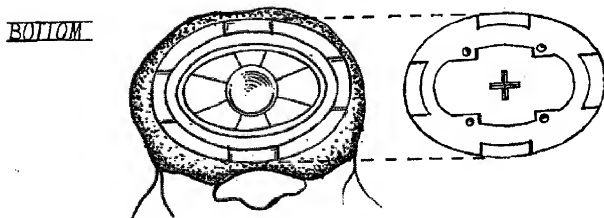
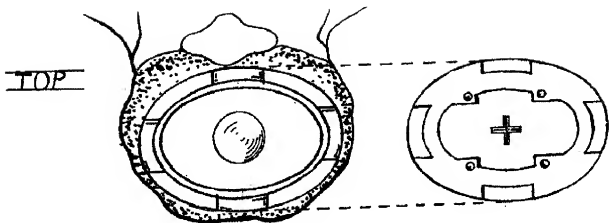
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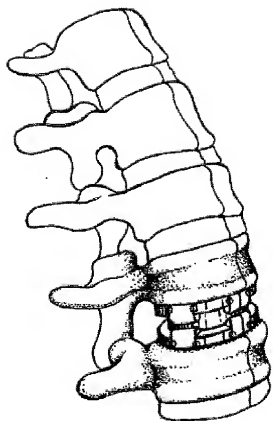
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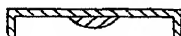
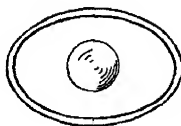
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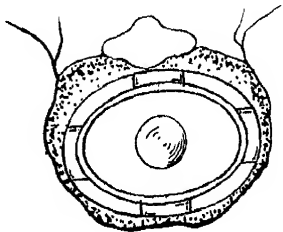
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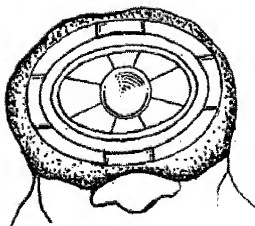


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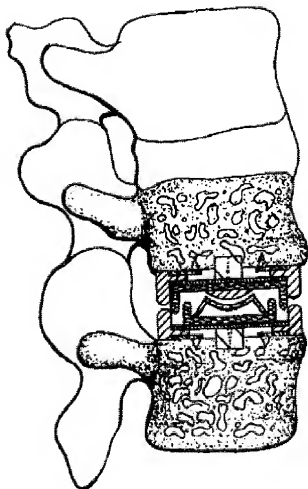
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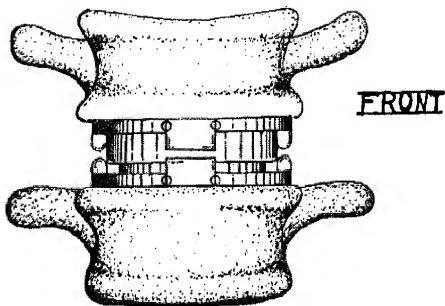
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Bohman, Monica J.



From: Manning, Michelle
Sent: Tuesday, June 24, 2003 9:41 PM
To: 'PJPSweeney@aol.com'
Cc: Green, Edward; Martin, Matthew E.; Kassel, Mark A.; Bohman, Monica J.
Subject: Patent Application for Prosthetic Disc System (Our ref. 029815-0101)

Dear Dr. Sweeney,

Attached please find a draft of the above-referenced patent application. You will notice that I have largely re-drafted the claims. I believe the new claims are both broader and more clear than the original set. I still have several remaining questions which are highlighted throughout the text. The figures referred to in the application correspond to the figures you faxed to us. However, the parts have been renumbered. I will fax copies of the figures with the revised figure and part numbers for your convenience tomorrow. These figures will be rough. Eventually, we will have to prepare cleaner figures.

I would like to speak with you regarding this application. In particular, I would like to go over some of the definitions with you and discuss some prior art devices. I will email several patents to you tomorrow. It would be helpful if you could review these patents so we can discuss them. I will be out of the office tomorrow (Wednesday) and Friday. Please let me know your availability early next week so I can set up a conference call. I will likely add more claims to the application after we have spoken.

As always, if you have any immediate questions or concerns with regard to this matter please do not hesitate to contact me.

Michelle Manning

Foley & Lardner
150 E. Gilman Street
Madison, WI 53701
Phone: (608) 258-4305
Fax: (608) 258-4258

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